K031838

OCT 3 0 2003

510(K) SUMMARY
(As required by section 21 CFR 807.92(c))

Submitter's name:	BioGeneration®, Inc.
Submitter's address:	9160 Highway 64, Suite 12, Lakeland, TN 38002
Submitter's telephone number:	(901) 380-9411
Contact Person:	Bernard F. Grisoni
Submission date:	June 12, 2003
Trade Name:	ProFusion® Bone Graft Substitute Kits
Common Name:	Calcium Sulfate
Classification Name:	Unclassified
Device Product Code and Panel Code:	Orthopedics/87/MQV
Legally marketed predicate devices:	ProFusion® Graft Substitute Devices Wright Medical Kits

Device description:
ProFusion® Bone Graft Substitute Kits consist of pre-measured medical grade calcium sulfate powder and pre-measured mixing solution, and the tools necessary to mix the components into a paste. The device is provided sterile for single use only. When its components are mixed according to the instructions, the ProFusion Kits produce biodegradable, radiopaque paste/molded pellets that resorb in approximately 30-60 days, when used according to labeling.

After the powder is hydrated using all of the mixing solution supplied in each kit, the resultant paste can be injected, digitally packed into the bone void to cure in-situ; or molded into solid implants that are gently packed into non-load bearing voids or gaps of the skeletal system (i.e. long bones, extremities, spine and pelvis). These bone voids or gaps may be either surgically created or result from traumatic injury. The implants provide a bone void filler that resorbs and is replaced with bone during the healing process.

Intended Uses/Indications:
The paste resulting from ProFusion® Bone Graft Substitute Kits is intended to be injected, digitally packed into bone voids or gaps to cure in-situ; or molded into solid pellets that are gently packed into bone voids or gaps that are not intrinsic to the stability of the bony structure of the skeletal system (i.e. long bones, extremities, spine and pelvis). These bone voids or gaps may be either surgically created or result from traumatic injury. The device provides a bone void filler that resorbs and is replaced with bone during the healing process.

ProFusion® paste cured in situ provides an bone void or gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary scaffold and is not intended to provide support during the healing process.

ProFusion® Bone Graft Substitute Kit s are provided sterile for single use only. Because the device is biodegradable and biocompatible, ProFusion® Bone Graft Substitute Kits may be used at an infected site.

Technological characteristics:
ProFusion® Bone Graft Substitute Kits have the equivalent chemical composition and technological characteristics to the predicate devices.

Performance data:
Testing demonstrated that the performance of the ProFusion® Bone Graft Substitute Kits are substantially equivalent to the performances of the predicate devices.

Basis for substantial equivalence:
The ProFusion® Bone Graft Substitute Kits are safe and effective because they are equivalent to the predicate devices in terms of chemical composition, indication of use, performances and design features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

Bernard Grisoni, Ph.D
Technical Service Director
BioGeneration, Inc.
9160 Highway 64, Suite 12
Lakeland, TN 38002

Re: K031838
Trade Name: ProFusion™ Bone Graft Substitute Kits
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: October 8, 2003
Received: October 9, 2003

Dear Dr. Grisoni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

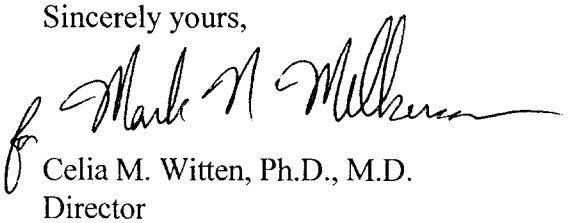
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K031838

Device Name: ProFusion® Bone Graft Substitute Kits

Indications For Use:
The paste made with the ProFusion® Bone Graft Substitute Kits are intended to be injected, digitally packed into bone voids or gaps; or molded into solid pellets that are gently packed into bone voids or gaps that are not intrinsic to the stability of the bony structure of the skeletal system (i.e. long bones, extremities, spine and pelvis). The bone voids or gaps may be either surgically created or result from traumatic injury. The device provides a bone void filler that resorbs and is replaced with bone during the healing process.

ProFusion® paste cured in situ provides a bone void or gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary scaffold and is not intended to provide support during the healing process.

ProFusion® Bone Graft Substitute Kits are provided sterile for single use only. Because the devices are biodegradable and biocompatible, they may be used at an infected site.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhean

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031838

Prescription Use ____ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)